Lexington Clinic

December 16, 1999

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Document Management Branch (HFA-3 5) Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville Maryland 20852

RE: Docket #97N-484S

To Whom It May Concern:

This letter is written regarding the proposal for FDA to regulate some type of allograft as medical devices.

Currently bone banks provide bone as tissue for which the FDA regulates the safety. I personally have used allograft bone for approximately 15 years. During that period I have had virtually no problems with the use of allograft bone. The availability of allograft bone is crucially important in surgery particularly in neurological spine surgery. Allograft bone has been used by many doctors over the years and virtually no problems have been encountered in the proper use of allograft bone as it is now supplied. I do not see any need for further FDA regulation of allograft bone. Bone banks likely do not have the resources or the expertise to satisfied the FDA's premarket requirement such as sponsoring clinical trials and submitting lengthy regulatory documents. I suspect that if they were required to do so this would lead to a curtailed supply of bone products&n which we rely for treating many patients. The potential for a reduced supply of allograft bone would have serious consequences for our patients.

Sincerely yours,

Leon J. Ravvin, M.D., C.M., F.R.C.S.(C)
LJR/lmt
1216/1217

NEUROSURGERY

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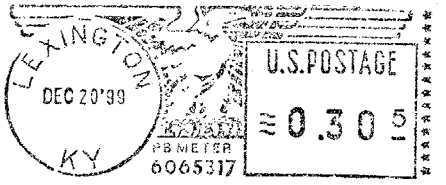

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